REMARKS

The invention relates to a disease model comprising a transgenic mouse and a sperm cell comprising a mammalian retrotransposon.

Claims 34, 36-44, 46, 47 and 49 are currently pending. Claims 34 and 36-43 have been amended to recite a disease model. Support for this amendment can be found beginning on page 37, where the transgenic mouse is useful for assessment of mutagenic potential in an animal, methods of identifying a compound having anti-mutagenic activity, methods of drug design, and the like. Accordingly, the specification sufficiently supports a disease model comprising a transgenic mouse.

Claims 34 and 44 have also been amended to indicate that the DNAc molecule comprises a promoter P and an L1 cassette sequence comprising a core L1 retrotransposon element flanked by loxP sites. Furthermore, claims 34 and 44 have been amended to indicate that the L1 retrotransposon element is useful for transferring of a desired DNA sequence. Support for these amendments is found throughout the specification. For example, the specification on page 33, lines 10-16 discloses that L1 can be flanked with loxP sites. Beginning on page 16, the specification discloses that L1 elements of the invention can be used to transfer desired genes to an animal (*e.g.*, correction of a genetic defect, generation of mutations, etc). As such, no new matter has been added by way of these amendments.

Rejection of claims 34, 36-44, 46, 47 and 49 under 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claims 34, 36-44, 46, 47 and 49 pursuant to 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement. Specifically, the Examiner is of the opinion that the specification fails to provide an enabling disclosure for the claimed transgenic mouse because the phenotype of the mouse is unpredictable, and therefore, in the Examiner's view, the specification does not teach how to use the claimed transgenic mouse. The Examiner asserts that in the absence of an "appropriate phenotype", the skilled artisan would not know how to use the claimed transgenic mouse. The Examiner also writes that "[t]he only utility asserted in the specification that rises to the level of a specific and substantial utility is the use of the transgenic mouse as a disease model." For this reason, the Examiner has not levied a rejection under 35 U.S.C. §101.

Applicants, while not wishing to acquiesce to the Examiner's reasoning, but rather in a good faith effort to expedite the prosecution of the present application, have amended claims 34 and 44 as discussed above. As such, the claims in some instances encompass a transgenic mouse useful in the context of being an experimental model for a particular gene of interest or otherwise a disease model associated with the transferred gene.

It is hornbook law that "If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that the standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied." MPEP §2164.01(c). *See also In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965); *In re Brana*, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993).

The same section of the MPEP also provides:

> [W]hen a compound or composition claim is not limited by a recited use, *any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use*. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention. (Emphasis added)

Applicants respectfully submit that the use of the claimed transgenic mouse and sperm cell, set forth in the specification as filed and further elucidated below, reasonably correlate scope of the amended claims and therefore preclude the Examiner's rejection based on how to use the claimed transgenic mouse and sperm cell.

The specification as filed sufficiently supports the use for the transgenic mouse and sperm cell presently claimed. As an example, on page 16, beginning at line 7, there is described a use for the transgenic animal, or the cells thereof, for random insertional mutagenesis in the animal. At page 20, beginning at line 24, the specification as filed discloses the use of a transgenic animal comprising a DNAc molecule useful for generating mutations in a cell and for the generation of transposon mutagens. Beginning at page 27, line 22, the specification as filed describes making and *using* transgenic mice comprising a DNAc molecule for generating high frequency mutation. As is further described at page 28, beginning at line 4, this high frequency

mutation can be *used* to provide mutations in a variety of genes, including genes which provide resistance or susceptibility to tumor development. Thus, the skilled artisan, when equipped with Applicants' disclosure and the Examples set forth therein, could *use* the transgenic mammal and the sperm presently claimed to transfer desired genes in which the DNAc molecule integrated to generate a type of disease model.

The claims, as amended and presently under consideration, are enabled and Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection pursuant to 35 U.S.C. §112, first paragraph, for lack of enablement.

Summary

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has been overcome or is now inapplicable, and that claims 34, 36-44, 46, 47 and 49 are now in condition for allowance. Applicants further submit that no new matter has been added by way of the present amendment. Reconsideration and allowance of these claims is respectfully requested at the earliest possible date.

Respectfully submitted,

Haig Kazazian *et al.*

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(Date)

By: _____

KATHRYN DOYLE, PH.D, J.D.
Registration No. 36,317
DRINKER, BIDDLE & REATH, LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
Telephone: (215) 988-2700
Direct Dial: (215) 988-2902
Facsimile: (215) 988-2757
E-Mail: Kathryn.Doyle@dbr.com
Attorney for Applicant

KD/QDN

Enclosures: Petition for Three (3) Month Extension of Time
Request for Continued Examination